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DP BAR CODE NO.: 386990
PC Code(s): 122990
FOOD Use: Yes

FILE SYMBOL NO.: 352-842 DECISION NO.: 445238
ACTION CODE: R340
NON-FOOD Use: Yes

DATE OUT: May 30, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: Mesotrione 50WG Herbicide

FROM: Hari Mukhoty
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

Handwritten: jme. 5/31/11

TO: Kathryn Montague / Michael Walsh PM - 23
Herbicide Branch / Registration Division (7505P)

Company Name: E. I Du Pont
Formulation Type: Solid Granules

INTRODUCTION:

The Registrant has submitted one revised basic CSF (dated: 02/09/2011), two amended CSFs to the aforesaid basic (dated: 02/09/2011) as alternate formulations (Alt. A1 and Alt. A2) and has proposed a product specific label for updating registration of the aforesaid products under EPA Reg. No. 352-842.

The basic product was previously registered as a 100% re-pack of EPA Reg. No. [REDACTED]. Now, Du Pont wants to formulate this product on their own and therefore has submitted product chemistry data under MRID(s): 477150-01 and -02 to update the registration of their revised formulations. In this submission, the registrant is proposing to use the alternate formulation A1 as a 100% re-pack of EPA Reg. No. [REDACTED]. However, alternate formulation A2 is not a re-pack product. A2 is a new formulation close to the basic product in composition with the use of few different inert ingredients.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed products.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Mesotrione (50.0%).
2. Has the registrant claimed substantial similarity to registered product?
☐ Yes ☒ No ☐ NA If yes: EPA Reg. No.
3. The source material(s) of the active ingredient(s) is/are registered with the Agency.
4. All inert ingredients have been screened by IIAB on 02/18/2011 and were approved for food uses (pre-harvest application to growing crops for control of broadleaf weeds).
5. The CSFs of the proposed basic and alternate formulations have been filled out completely and correctly.

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6. Confidential Statement of Formula(s):

☒ Basic - Dated: 02/09/2011 re-submitted – Dated: NA

☒ Alternate- A1 and A2 Dated: 02/09/2011 re-submitted: Dated: NA

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No NA ☐. The certified limits of the active ingredient used in the Alt. A1 are not similar to the basic product.

7. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"

, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid equivalent: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label has a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☐ No ☒ NA

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No – from product chemistry point of view; if yes explain below:

Final decision of overall label acceptance will be made by the PM.

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8. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. 477150-01, -02
			Yes	No		
830.1550	Product Identity & Composition		X		A	"
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X		A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis			X	NA	"
830.1750	Certified limits (158.350)	Standard certified Limits				
		Justification for wider limits		X	A	
830.1800	Enforcement analytical method #		X		A	477150-02

A = Acceptance, NA = Not Acceptable, G = Data Gap,
 W = Waiver Request, I = In Progress, NA = Not Applicable
 # Analytical Method: HPLC using UV Detector set at 230 nm.

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9. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos. 477150-02
830.6303	Physical State	Solid granules	A	"
830.6315	Flammability	Does not contain flammable components; Flash point > 185°F	A	"
830.6316	Explodability	Does not have explosive characteristics	A	"
830.7000	pH	4-6 (1% sol @ 25.°C)	A	"
830.7300	Density (units)	0.5 – 0.6 g/ml @ 20.0°C	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress

CONCLUSIONS:

1. TRB has reviewed the CSFs (dated: 02/09/2011) for the proposed basic and alternate formulations and has found them to be acceptable. The CSFs are attached with this review and can be located in OPPIN CHEM DOCS.
2. Product chemistry Group A and Group B data, with the exception of one year storage stability (830.6317), and corrosion characteristics (830.6320) are satisfied and acceptable.
3. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.
4. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.

